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| 10/030,877      | 04/22/2002  | Paul David James Blackler | P32293              | 6105             |

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EXAMINER

HABTE, KAHSAY

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1624

DATE MAILED: 07/11/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/030,877

Applicant(s)

BLACKLER ET AL.

Examiner

Kahsay Habte, Ph. D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other:

### **DETAILED ACTION**

1. Claims 1-10 and 14 are pending.

### ***Specification***

2. On page 2 (line 1) of the specification, the phrase " n X-ray powder" is incorrect.

### ***Objection***

3. Claims 2-5 are objected as being duplicates of claim 1. Claim 1 and claims 2-5 both recite the characteristics (Raman Spectrum, solid-state nuclear magnetic resonance spectrum and X-ray powder diffraction) of the polymorph, thus they are duplicates. There is only one polymorph, so all these claims must be describing the same thing.
4. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 recites a polymorphic form of the thiazolidine derivative of maleic acid salt and since the d spacing indicates that the polymorph are crystalline, the term "crystalline" in claim 8 does not narrow down the limitation of claim 1.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There has been recited prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof, but the specification is not enabled for such a scope. To this day, the only thing available is to treat patients that are diabetic, but not preventing someone from getting diabetes mellitus.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Pool et al. (WO 94/05659). Said reference teaches the synthesis of substituted thiazolidinedione derivatives. Specifically, on page 8 (Example 2) the cited reference

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teaches the following salt:

5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid

that is the same as applicants.

Claims 1-8 are product claims, in which applicants recite some of the physical and chemical characteristics of the said product. MPEP 2112 says:

"SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

In this case, the "unknown property" is the particular crystalline form with X-ray diffraction pattern, with IR and Raman spectra containing peaks, and with a solid-state nuclear magnetic resonance spectrum containing peaks. This is unknown because the reference is silent on this property. MPEP 2112 goes on to state:

"A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection."

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Again, the "CHARACTERISTIC" which the prior art is silent on is the crystalline form.

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also Ex parte Anderson, 21 USPQ 2<sup>nd</sup> 1241 at 1251.

Applicants are reminded that the PTO has no testing facilities. If applicants' reasoning were accepted, then any anticipation rejection of an old compound could always be overcome by tacking on some characteristic or property which the reference was silent on, regardless of whether the prior art material was any different from the claimed material. For example, if it did not happen to mention the color, one could patent an old compound just by adding "which is green" or "which is not indigo". One could put in a limitation about density (e.g. "density is not 1.4"), melting point, "refractive index of 2.0", solubility in some obscure solvent, spectroscopic data, and then simply point to the silence of the reference, as applicants have done here. Or one could add properties like or "does not explode on tapping" or "in the form of microneedles" or, as here, "crystals have characteristic diffraction peaks in the X-ray diffraction pattern."

In regard to claim 10, the pharmaceutical composition in the form of a water solution of a polymorph and water is the same as a pharmaceutical composition in the form of water solution of the salt itself. Once dissolved in a solvent, the pharmaceutical composition is the same regardless of the original form.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claims 4-5, applicants recite "Figure III/or Table I" and "Figure IV/or Table II", but it is unclear what they are. It is recommended that applicants include only the Tables or content of the Tables from the specification in the claims. Like wise, the same problem exists in claim 2.

b. In claim 6, the phrase "isolated form" is not clear. Isolated from what?

c. In claim 7, the phrase "in pure form" is not clear. Said term represents term of degree to describe the purity of the polymorph, but there is no guidance in the specification. What constitutes the purity of polymorphs? What is the criteria for a polymorph to be pure? One skilled in the art would not be able to recognize a polymorph as "pure form" or impure form. How pure is considered as "pure form"? Is 70% pure considered as "pure"? 90%?? 99%? 99.9%? Where is the line?

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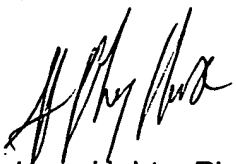
d. In claim 14, the phrase "conditions associated with diabetes mellitus and certain complications thereof" is indefinite. What conditions are covered and what are not? How can one tell which complications are covered and which are not?

**Conclusion**

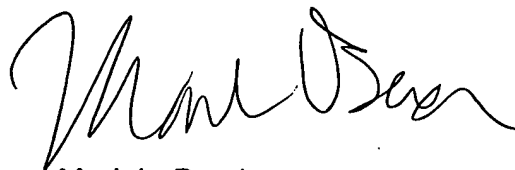
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624



Mark L. Berch  
Primary Examiner  
Art Unit 1624

KH  
July 2, 2003